510(k) SUMMARY

1. Date: September 26, 2013

2. 510(K) Number: k132630

3. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
South China University of Technology
Guangzhou, P.R. China 510641

4. Contact person: Joe Shia
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SEP 27 2013

5. Device Name: Wondfo Methamphetamine Urine Test (MET 300)
Wondfo Oxazepam Urine Test (BZO 200)

Classification: Class II

Product Code	CFR #	Panel
DJC	21 CFR 862.3610 Methamphetamine Test System	Toxicology
JXM	21 CFR 862.3170 Benzodiazepine Test System	Toxicology

6. Predicate Devices:
K050394
Medtox Diagnostics Sure-Screen

7. Intended Use
Wondfo Methamphetamine Urine Test (MET 300) is an immunochromatographic assay for the qualitative determination of D(+)-Methamphetamine in human urine at a Cut-Off concentration of 300 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Wondfo Oxazepam Urine Test (BZO 200) is an immunochromatographic assay for the qualitative determination of Oxazepam in human urine at a Cut-Off concentration of 200 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

8. Device Description

Immunochromatographic assays for Methamphetamine and Oxazepam Urine Tests use a lateral flow, one step system for the qualitative detection of D(+)-Methamphetamine and Oxazepam (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes. Oxazepam is part of the Benzodiazepine class of drugs of abuse.

9. Substantial Equivalence Information

A summary comparison of features of the Wondfo Methamphetamine Urine Test (MET 300) and Wondfo Oxazepam Urine Test (BZO 200) and the predicate device is provided in Table 1.

Table 1: Features Comparison of Wondfo Methamphetamine Urine Test (MET300) and Wondfo Oxazepam Urine Test (BZO 200) and the Predicate Device

Item	Device	Predicate - K050394
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine. For prescription use.	Same
Calibrator	D(+)-Methamphetamine and Oxazepam	D(+)-Methamphetamine and Nordiazepam
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300 ng/mL(MET) and 200 ng/mL (Oxazepam/BZO)	Same
Configurations	Cup, Dip Card	Cup

10. Test Principle

It is a rapid test for the qualitative detection of D(+)-Methamphetamine and Oxazepam in urine samples. It is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentration below the target cut off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cutoff, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in the test region, indicating a potentially positive result.

11. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100%cut off, -75%cut off, -50%cut off, -25%cut off, +25%cut off, +50%cut off , +75%cut off and +100%cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blinded labeled by the person who prepared the samples and that person did not take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following tables.

Cup Format

MET 300

Result / MET 300	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
LOT W1171001 CU2	50-/0+	50-/0+	50-/0+	50-/0+	47+/3-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1171002 CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1171003 CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

Oxazepam **BZO 200**

Result / BZO 200	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
LOT W0970901 CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W0970902 CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W0970903 CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

MET 300

Result / MET 300	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
LOT W1171001 P	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1171002 P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1171003 P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

Oxazepam **BZO 200**

Result / BZO 200	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
LOT W0970901 P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W0970902 P	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W0970903 P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable

c. Stability

The test devices are stable at 4-30°C for 18 months based on the accelerated stability study at 50°C and real time stability determination at both 4°C and 30°C.

d. Cut-off

A total of 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for both Methamphetamine and Oxazepam. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Wondfo Methamphetamine Urine Test (MET 300)	D(+)-Methamphetamine	300
Wondfo Oxazepam Urine Test (BZO 200)	Oxazepam	200

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine

with concentration at 25% below and 25% above Cut-Off level respectively. These urine samples were tested using three batches of each device for both Dip Card and Cup formats.

Compounds that show no interference at a concentration of 100 µg/mL are summarized in the following tables. There are no differences observed for both Dip Card and Cup formats.

MET 300

Acetamidophen	Gentisic acid	Oxycodone
Acetophenetidin	Glucuronide	Oxymetazoline
N-Acetylprocainamide	Glutethimide	Papaverine
Acetylsalicylate	Guaifenesin	Penicillin-G
Aminopyrine	Hippuric acid	Pentazocine
Amitryptyline	Hydralazine	Pentobarbital
Amobarbital	Hydrochlorothiazide	Perphenazine
Amoxicillin	Hydrocodone	Phencyclidine
Ampicillin	Hydrocortisone	Phenelzine
Apomorphine	O-Hydroxyhippuric acid	Phenobarbital
Aspartame	3-Hydroxytyramine	Prednisolone
Atropinne	Ibuprofen	Phenylpropanolamine
Benzilic acid	Imipramine	Prednisone
Benzoic acid	(-) Isoproterenol	Procaine
Benzoylecgonine	Isoxsuprine	Promazine
Butabartital	Ketamine	Promethazine
Cannabidiol	Ketoprofen	D,L-Propanolol
Chloralhydrate	Labetalol	D-Propoxyphene
Chloramphenicol	Levorphanol	D-Pseudoephedrine
Chlordiazepoxide	Loperamide	Quinidine
Chlorothiazide	Loxapine succinate	Quinine
Chlorpromazine	Maprotiline	Ranitidine
Cholesterol	Meperidine	Salicylic acid
Clomipramine	Meprobamate	Secobarbital
Clonidine	Methadone	Serotonin (5- Hydroxytyramine)
Cocaine hydrochloride	Methaqualone	Sulfamethazine
Codeine	Methylphenidal	Sulindac
Cortisone	Methyprylon	Temazepam
(-) Cotinine	Morphine-3-β-Dglucuronide	Tetracycline
Creatinine	Nalidixic acid	Tetrahydrocortisone, 3-Acetate
Deoxycorticosterone	Nalorphine	Tetrahydrocortisone 3 (β-D glucuronide)
Dextromethorphan	Naloxone	Tetrahydrozoline
Diazepam	Naltrexone	Thebaine
Diclofenac	Naproxen	Thiamine

Diflunisal	Niacinamide	Thioridazine
Digoxin	Nifedipine	Tolbutamine
Diphenhydramine	Norcodein	Triamterene
Doxylamine	Norethindrone	Trifluoperazine
Ecgonine hydrochloride	Noroxymorphone	Trimethoprim
Ecgonine methyl ester	D-Norpropoxyphene	Trimipramine
Erythromycin	Noscapine	D, L-Tryptophan
β-Estradiol	Nylidrin	Tyramine
Estrone-3-sulfate	D,L-Octopamine	D, L-Tyrosine
Ethyl-p-aminobenzoate	Oxalic acid	Uric acid
Fenoprofen	Oxazepam	Verapamil
Furosemide	Oxolinic acid	Zomepirac

Oxazepam **BZO 200**

4-Acetamidophenol	Diphenhydramine	Oxalic acid
Acetophenetidin	Doxylamine	Oxolinic acid
N-Acetvprocainamide	Ecaonine dydrochloride	Pentobarbital
Acetvsalicvlic acid	Ecqonine methylester	Perphenazine
Aminopvrine	(-)-Y-Ephedrine	Phencyclidine
Amityptvline	Fenoprofen	Phenelzine
Amorbarbital	Furosemide	Phenobarbital
Amoxicillin	Gentisic acid	Phentermine
Ampicillin	Hemoglobin	L-Phenylephrine
l-Ascorbic Acid	Hydrocortisone	b-Phenylethylamine
D.L-Amphetamine	O-Hydroxyhippuric acid	Phenylpropanotamine
Apormorphine	p-Hydroxy- methamphetamine	Prednisone
Aspartame	3-Hydroxytyramine	D.L-Propanolol
Atropine	Ibuprofen	D-Propoxyphene
Benzillic acid	Imipramine	D-Pseudoephedrine
Benzoic acid	Iproniazid	Quinine
Benzoylecaonine	(±)Isoproterenol	Ranitidine
Benzphetamine	Isoxsuprine	Salicylic acid
Bilirubin	Ketamine	Secobarbital
(±) Chlorpheniramine	Ketoprofen	Serotonin (5-Hydroxytyramine)
Caffeine	Labetalol	Sertraline
Cannabidiol	Loperamide	Sulfamethazine
Chloralhvdrate	Maprotiline	Sulindac
Chloramphenicol	Meperidine	Tetrahydrocortisone,3 Acetate
Chlordiazepoxide	Meprobamate	Tetrahydrocortisone,(b-D glucuronide)
Chlorothiazide	Methadone	Tetrahydrozoline
(±)Chlorpheniramine	Methoxyphenamine	Thiamine
Chlorpromazine	(+) 3,4-Methylenedioxy-	Thioridazine

	amphetamine	
Chlorquine	(+)3,4-Methylenedioxy-methamphetamine	D.L-Tyrosine
Cholesterol	Nalidixic acid	Tolbutamide
Clomipramine	Nalorphine	Triamterene
Clonidine	Naloxone	Trifluoperazine
Cocaine hydrochloride	Naltrexone	Trimethoprim
Cortisone	Naproxen	Triyptamine
(-)cotinine	Niacinamide	D.L-Tryptophan
Creatinine	Nifedipine	Tyramine
Dextromethlorphan	Norethindrone	Uric acid
Diclolrfenac	D-Norpropoxyphene	Verapamil
Diflunisal	Noscapine	Zomepirac
Digoxin	D.L-Octopamine	

f. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for both Dip Card and Cup formats. Compounds that produced positive results are listed below. There are no differences observed for both Dip Card and Cup formats.

MET 300

MET(Methamphetamine) (D(+)-Methamphetamine, Cut-off=300 ng/mL)	**Minimum Concentration Required to Obtain a Positive Result (ng/mL)**	**% Cross-Reactivity**
D(+)-Methamphetamine	300	100%
D-Amphetamine	40,000	<1%
Chloroquine	8,000	3.8%
(+/-)-Ephedrine	20,000	1.5%
(-)-Methamphetamine	8,000	3.8%
(+/-)3,4-methylenedioxumethamphetamine(MDMA)	800	37.5%
β-Phenylethylamine	10,000	3%
Trimethobenzamide	3,000	10%

Oxazepam **BZO 200**

BZO(Oxazepam) (Oxazepam, Cut-off=200 ng/mL)	**Minimum Concentration Required to Obtain a Positive Result (ng/mL)**	**% Cross-Reactivity**
Oxazepam	200	100%
Alprazolam	50	400%
a-Hydroxyalprazolam	500	40%
Bromazepam	500	40%
Chlordiazepoxide	800	25%
Clonazepam HCl	400	50%
Clobazam	50	400%
Clonazepam	400	50%
Clorazepate dipotassium	50	400%
Delorazepam	500	40%
Desalkylflurazepam	200	100%
Diazepam	50	400%
Estazolam	1000	20%
Flunitrazepam	200	100%
D,L-Lorazepam	800	25%
Midazolam	5000	4%
Nitrazepam	50	400%
Norchlordiazepoxide	100	200%
Nordiazepam	200	100%
Temazepam	50	400%
Triazolam	500	40%

g. Effect of Urine Specified Gravity and Urine pH

To investigate the effect of urine specified gravity and urine pH, the urine samples, with 1.000~1.035 specified gravity or urine samples with pH 4~9 were spiked with target drugs at 25% below and 25% above Cut-Off level, respectively. These samples were tested using three batches of each device for both Dip Card and Cup formats. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed for both Dip Card and Cup formats.

2. Comparison Studies

The method comparison for the Wondfo Methamphetamine Urine Test (MET 300), Wondfo Oxazepam Urine Test (BZO 200) was performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the table below:

MET 300:

Cup Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and Cut-off)	Near Cut-off Positive by GC/MS (Between the Cut-off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	Positive	0	0	2	21	19
	Negative	10	11	17	0	0
Viewer B	Positive	0	0	2	21	19
	Negative	10	11	17	0	0
Viewer C	Positive	0	0	2	21	19
	Negative	10	11	17	0	0

Dip Card Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and Cut-off)	Near Cut-off Positive by GC/MS (Between the Cut-off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	Positive	0	0	3	21	19
	Negative	10	11	16	0	0
Viewer B	Positive	0	0	2	21	19
	Negative	10	11	17	0	0
Viewer C	Positive	0	0	3	21	19
	Negative	10	11	16	0	0

Discordant Results of MET 300

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer A	MET3212	294	Positive
Viewer A	MET3214	293	Positive
Viewer B	MET3212	294	Positive
Viewer B	MET3213	294	Positive
Viewer C	MET3062	281	Positive
Viewer C	MET3213	294	Positive

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	MET3062	281	Positive

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	MET3212	294	Positive
Viewer A	MET3213	294	Positive
Viewer B	MET3212	294	Positive
Viewer B	MET3213	294	Positive
Viewer C	MET3061	280	Positive
Viewer C	MET3062	281	Positive
Viewer C	MET3214	293	Positive

Oxazepam **BZO 200:**

Cup Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and Cut-off)	Near Cut-off Positive by GC/MS (Between the Cut-off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	**Positive**	0	0	2	22	18
	Negative	10	18	10	0	0
Viewer B	**Positive**	0	0	1	22	18
	Negative	10	18	11	0	0
Viewer C	**Positive**	0	0	1	22	18
	Negative	10	18	11	0	0

Dip Card Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-off Negative by GC/MS (Between -50% and Cut-off)	Near Cut-off Positive by GC/MS (Between the Cut-off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	**Positive**	0	0	2	22	18
	Negative	10	18	10	0	0
Viewer B	**Positive**	0	0	2	22	18
	Negative	10	18	10	0	0
Viewer C	**Positive**	0	0	2	22	18
	Negative	10	18	10	0	0

Discordant Results of Oxazepam **BZO 200**

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer A	BZO2065	182	Positive
Viewer A	BZO2063	186	Positive

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer B	BZO2063	186	Positive
Viewer C	BZO2062	178	Positive

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	BZO2062	178	Positive
Viewer A	BZO2063	186	Positive
Viewer B	BZO2062	178	Positive
Viewer B	BZO2065	182	Positive
Viewer C	BZO2063	186	Positive
Viewer C	BZO2216	171	Positive

3. Clinical Studies

   Not applicable

Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that Wondfo Methamphetamine Urine Test (MET 300) and Wondfo Oxazepam Urine Test (BZO 200) are substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Guangzhou Wondfo Biotech Co., Ltd.
c/o Joe Shia
504 East Diamond Ave.
Suite F
GAITHERSBURG MD 20878

Re: K132630
Trade/Device Name: Wondfo Methamphetamine Urine Test (MET 300)
Wondfo Oxazepam Urine Test (BZO 200);
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: II
Product Code: DJC, JXM
Dated: August 11, 2013
Received: August 22, 2013

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k132630

Device Name: Wondfo Methamphetamine Urine Test (MET 300)
Wondfo Oxazepam Urine Test (BZO 200)

Indications for Use:

Wondfo Methamphetamine Urine Test (MET 300)

Wondfo Methamphetamine Urine Test (MET 300) is an immunochromatographic assay for the qualitative determination of D(+)-Methamphetamine in human urine at a Cut-Off concentration of 300 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.09.27 12:56:24 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132630

Indications for Use

510(k) Number (if known): k132630

Device Name: Wondfo Methamphetamine Urine Test (MET 300)
Wondfo Oxazepam Urine Test (BZO 200)

Indications for Use:

Wondfo Oxazepam Urine Test (BZO 200)

Wondfo Oxazepam Urine Test (BZO 200) is an immunochromatographic assay for the qualitative determination of Oxazepam in human urine at a Cut-Off concentration of 200 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.09.27 12:56:48 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132630